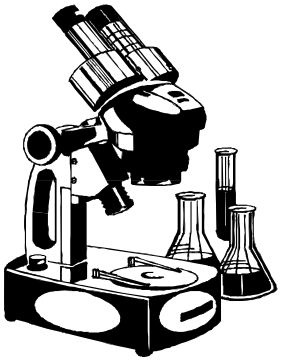

CLIA BITS

North Dakota Department of Health
Division of Health Facilities

Winter 2002

Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Jan. 1, 2001, through Dec. 31, 2001.

- The most common deficiency cited in 2001 was D7047, comparison of test results. This requirement states that if a laboratory performs tests that are not included under Subpart I, Proficiency Testing Program, the laboratory must have a system for verifying the accuracy and reliability of its test results twice a year.
- The second most common deficiency cited was D3056, test report. This requirement states that the test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.
- D4006 was the third most commonly cited deficiency. This requirement states that a laboratory must perform and document control procedures using at least two levels of control materials each day of testing.
- Test records, D3037, was the fourth most commonly cited deficiency. This deficiency is cited when a laboratory's record system fails to include the patient identification number, accession number or other unique identification number.
- The fifth most common deficiency cited was D7001. This requirement states that each laboratory performing moderate or high complexity testing, or both, must establish and follow written policies and procedures for a comprehensive quality assurance program designed to monitor and evaluate the ongoing and overall quality of the total testing process.

Take a close look at your laboratory and identify if your laboratory is also deficient in these areas, and, if so, take the corrective actions necessary to fix these areas prior to your next survey. If you have any questions about the deficiencies or the requirements, please contact the North Dakota Department of Health, Division of Health Facilities, at 701.328.2352.

CMS Updates Laboratory Reporting Requirements

On Nov. 28, 2001, the Centers for Medicare & Medicaid Services (CMS) updated the policy regarding a laboratory's responsibility to notify CMS of any changes in the tests it performs. Previously, a laboratory was allowed six months to notify CMS (or its designee) of any change in testing, including test additions, deletions and changes in test methodologies. The new policy requires a laboratory that wishes to begin testing outside of its approved specialties or subspecialties to notify CMS (or its designee) **prior** to initiating patient testing in the new specialty or subspecialty. CMS must then determine compliance and establish the date the laboratory is approved to perform patient testing in the new specialty or subspecialty. The CMS designee is the state survey agency or an accreditation organization. The notification must be in writing and must be signed by the laboratory director.

CMS Updates Valid Application Types

On Nov. 28, 2001, the Centers for Medicare & Medicaid Services (CMS) clarified the policy regarding laboratories that choose affiliation with a CMS-approved accrediting organization for some testing and with the state agency for their remaining testing. The new policy requires a laboratory performing moderate and/or high complexity testing to choose either a Certificate of Compliance or a Certificate of Accreditation. If one accreditation organization does not cover all of the testing performed by a laboratory, the laboratory must choose one of three options. The laboratory may choose an additional accreditation organization to cover the remaining testing, choose a different accreditation organization that covers all testing or choose to be certified by CMS for all testing performed.

CLIA Waived Laboratories To Be Surveyed

On Nov. 7, 2001, it was announced that CMS is initiating on-site visits to approximately 2 percent of waived facilities enrolled in CLIA. The on-site visits to waived facilities is due to survey results of CLIA-waived and Provider Performed Microscopy Procedures (PPMP) laboratories during a CMS pilot project. Significant quality and certification problems were identified in more than 50 percent of these laboratories. The results made evident the need for education and oversight of the waived laboratories to enhance the quality of laboratory services. The North Dakota Department of Health CLIA agency will conduct surveys of 2 percent of the CLIA-waived laboratories in North Dakota during 2002. Laboratories with a Certificate of Waiver must perform only testing that is categorized as waived and must follow the manufacturer's instructions for performing the test.

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